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PHA 42620.1 (01380/1/US)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Diane T. Stephenson et al.

Serial No. 10/828,868

Filed April 21, 2004

For COMPOSITIONS OF A CYCLOOXYGENASE-2 SELECTIVE INHIBITOR AND A CALCIUM MODULATING AGENT FOR THE TREATMENT OF CENTRAL NERVOUS SYSTEM DAMAGE

July 29, 2004

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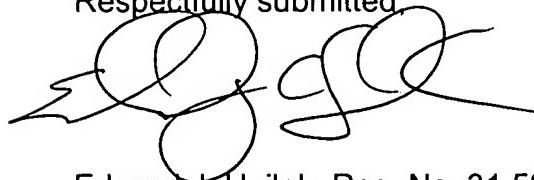
INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicants submit herewith copies of the foreign patent documents and literature references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

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Respectfully submitted,

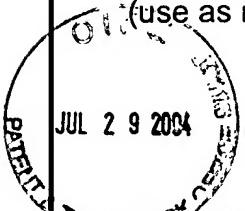


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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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of

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<i>Complete if Known</i>	
Application Number	10/828,868
Filing Date	April 21, 2004
Confirmation Number	
First Named Inventor	Diane T. Stephenson
Group Art Unit	
Examiner Name	
Attorney Docket No.	PHA 42620.1 (01380/1/US)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	1	3,261,859		Knoll A.-G.	07/19/1966
	2	3,267,104		Janssen Pharmaceutica N.V.	08/16/1966
	3	4,338,322		Sato	07/06/1982
	4	4,466,972		Neumann	08/21/1984
	5	4,521,537		Kosley, Jr. et al.	06/04/1985
	6	4,652,561		Mohacsi et al.	03/24/1987
	7	4,663,325		Ohtaka et al.	05/05/1987
	8	4,572,909		Campbell et al.	02/25/1986
	9	4,678,783		Hidaka et al.	07/07/1987
	10	4,845,225		Schwender et al.	07/04/1989
	11	4,935,417		Pascal et al.	06/19/1990
	12	5,314,903		Axelsson et al.	05/24/1994
	13	5,466,823		Talley et al.	11/14/1995
	14	5,521,207		Graneto	05/28/1996
	15	5,633,272		Talley et al.	05/27/1997

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	16	5,767,129		Yuen	06/16/1998
	17	5,932,598		Talley et al.	08/03/1999
	18	5,981,539		Axelsson et al.	11/09/1999
	19	6,034,256		Carter et al.	03/07/2000
	20	6,077,850		Carter et al.	06/20/2000
	21	6,306,912		Mueller	10/23/2001
	22	6,387,897		Snutch	05/14/2002
	23	6,423,689		Booth et al.	07/23/2002

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office	Number ⁴	Kind Code ² (if known)			
	24	EP	0072620	A1	Recordati S.A.	07/09/1982	
	25	EP	0089167	A2	Pfizer Limited	03/08/1983	
	26	EP	0092936	A1	Taisho Pharmaceutical Co. Ltd.	04/13/1983	
	27	EP	0125803	A2	Fisons Plc	04/16/1984	
	28	EP	0132375	A2	Pfizer Limited	07/18/1984	
	29	EP	0145434	A2	Otsuka Pharmaceutical Co., Ltd.	12/03/1984	
	30	EP	0173933 (abs)	A1	Satinger, Gerhard, Dr.	08/23/1985	

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	31	EP	0184257	A1	Janssen Pharmaceutica N.V.	11/22/1985	
	32	EP	0218996	A2	Yason S.r.L.	10/01/1986	
	33	EP	0257616	A2	The Green Cross Corporation	08/25/1987	
	34	EP	0358418	A1	Sankyo Company Limited	09/01/1989	
	35	EP	0366548	A1	Yuhan Corporation Ltd.	10/25/1989	
	36	EP	0372934	A2	The Wellcome Foundation Limited	12/06/1989	
	37	EP	0372940	A2	Allergan, Inc.	12/07/1989	
	38	EP	0400495	A1	Farmitalia Carlo Erba S.r.L.	05/25/1990	
	39	EP	0404359	A1	Pfizer Limited	05/25/1990	
	40	EP	0414421	A2	Richter Gedeon Vegyeszeti Gyar R.T.	08/09/1990	
	41	EP	0424901	A1	The Green Cross Corporation	10/24/1990	
	42	EP	0441539	A2	Tanabe Seiyaku Co., Ltd.	01/31/1991	
	43	EP	0467435	A2	Akzo N.V.	06/20/1991	
	44	EP	0520200	A2	Neurosearch A/S	05/27/1992	
	45	EP	0559569	A1	Bristol-Myers Squibb Company	03/04/1993	
	46	WO	91/07980	A1	Neurex Corporation	06/13/1991	
	47	WO	92/01672	A1	Novo Nordisk A/S	02/06/1992	
	48	WO	92/04338	A1	The UpJohn Company	03/19/1992	
	49	WO	92/14709	A2	Cambridge Neuroscience Inc.	09/03/1992	

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	50	WO	96/07415	A1	Universite De Montreal	03/14/1996	
	51	WO	96/07641 (abs)	A1	Nippon Shinyaku Co., Ltd.	03/14/1996	
	52	WO	97/45115	A1	Trophix Pharmaceuticals, Inc.	12/04/1997	
	53	WO	98/03484	A1	Merck Frosst Canada Inc.	01/29/1998	
	54	WO	99/54350	A1	The University of Queensland	10/28/1999	
	55	WO	99/55688	A1	Warner-Lambert Company	11/04/1999	
	56	WO	00/24719	A1	Abbott Laboratories	05/04/2000	
	57	WO	00/48584	A2	Ortho-McNeil Pharmaceutical, Inc.	08/24/2000	

OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	58	ALBERS, "Rationale for Early Intervention in Acute Stroke", American Journal of Cardiology, 1997, 804(4C): 4d-10d	
	59	DE VRIES et al, "The Antiinflammatory Activity of Topically Applied Novel Calcium-Channel Antagonists", Inflammation, 1995, 19(2): 261-275	
	60	GURBEL et al, "Increased Baseline Levels of Platelet P-Selectin, and Platelet-Endothelial Cell Adhesion Molecule-1 in Patients with Acute Myocardial Infarction as Predictors of Unsuccessful Thrombolysis", Coronary Artery Disease, 1998, 9(7): 451-456	
	61	HICKS et al, "Neuroprotective Effects of the Neuronal Ca ²⁺ channel blockers, LY042826 and LY393615 in Vivo", European Journal of Pharmacology, 2000, 408: 241-248	
	62	KRATZER et al, "Simulation of Primary Haemostasis in Vitro", Haemostasis, 1985, 15: 357-362	

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--------------------	-----------------

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	63	KOBAYASHI ^a et al, "Calcium-induced Mitochondrial Swelling and Cytochrome c Release in the Brain: Its Biochemical Characteristics and Implication in Ischemic Neuronal Injury", Brain Research, 2003, 960: 62-70	
	64	LAPCHAK et al, "Neuroprotection by the Selective Cyclooxygenase-2 Inhibitor SC-236 Results in Improvements in Behavioral Deficits Induced by Reversible Spinal Cord Ischemia", 2001, Stroke, 32(5): 1220-1230	
	65	NAGAYMA et al, "The Cyclooxygenase-2 Inhibitor NS-398 Ameliorates Ischemic Brain Injury in Wild-Type Mice but not in Mice with Deletion of the Inducible Nitric Oxide Synthase Gene", Journal of Cerebral Blood Flow Metabolism, 1999, 19(11): 1213-1219	
	66	NOGAWA et al, "Cyclo-Oxygenase-2 Gene Expression in Neurons Contributes to Ischemic Brain Damage", The Journal of Neuroscience, 1997, 17(8): 2746-2755	
	67	SONG et al, "(S)-4-Methyl-2-(methylamino)pentanoic Acid [4,4-Bis(4-fluorophenyl)butyl]amide Hydrochloride, a Novel Calcium Channel Antagonist, Is Efficacious in Several Animal Models of Pain", Journal of Medicinal Chemistry, 2000, 43(19): 3474-3477	
	68	TANAKA et al, "Effects of Blockade of Voltage-Sensitive Ca ²⁺ /Na ⁺ Channels by a Novel Phenylpyrimidine Derivative, NS-7, or CREB Phosphorylation in Focal Cerebral Ischemia in the Rat", 2000, Brain Research, 873(1): 83-93	

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